U. S. Department of Health and Human Services (DHHS)
Office for Human Research Protections (OHRP)

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

A. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS WITHIN THE UNITED STATES

1. Human Subject Research Must be Guided by Ethical Principles

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by Federal Departments and Agencies that have adopted the Federal Policy for the Protection of Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. The Institution becomes so engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of federally-supported research; or (c) the Institution receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

[*Federally-supported is defined throughout the FWA and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]

3. Compliance with the Federal Policy for the Protection of Human Subjects

Institutions conducting federally-supported human subject research and the IRB(s) designated under the Institution's Assurance will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subject research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

The reference in the Code of Federal Regulations is shown below for each Agency which has adopted the Common Rule:

7CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 123	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission
22 CFR 225	Agency for International Development
24 CFR 60	Department of Housing and Urban Development
28 CFR 46	Department of Justice
32 CFR 219	Department of Defense
34 CFR 97	Department of Education
38 CFR 16	Department of Veterans Affairs
40 CFR 26	Environmental Protection Agency
45 CFR 46	Department of Health & Human Services
45 CFR 690	National Science Foundation
49 CFR 11	Department of Energy
By Executive Order	Central Intelligence Agency
By Statue	Social Security Administration

4. Written Procedures

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

1) ensuring prompt reporting to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the Common Rule;

b) The designated IRB(s) has established, and will provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s). The IRB(s) will have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, informed consent will be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the Common Rule.

7. Requirement for Assurances for Collaborating Institutions/Investigators

The Institution is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

8. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigators who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

9. Institutional Support for the IRB(s)

The Institution will provide the IRB(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

10. Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-9 above and is responsible for ensuring that (a) the IRB(s) designated under the Assurance agree to comply with these terms; and (b) the IRB(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP guidance on IRB Knowledge of Local Research Context on the OHRP website).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

11. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator, and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these modules, prior to submitting the Assurance.

12. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

13. Renewal of Assurance

All information provided under this Assurance must be updated at least every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's FWA for the protection of human subjects.

DOMESTIC INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

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B. TERMS OF THE FEDERALWIDE ASSURANCE (FWA) FOR INTERNATIONAL (NON-U.S.) INSTITUTIONS

1. Human Subject Research Must Be Guided by Ethical Principles

All of the Institution's human subject activities and all activities of the Institutional Review Boards (IRBs) or independent ethics committees (IECs) designated under the Assurance, regardless of funding source, will be guided by one of the following statements of ethical principles: (a) The World Medical

Association's Declaration of Helsinki (as adopted in 1996 or 2000); (b) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; or (c) other appropriate international ethical standards recognized by Federal Departments and Agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects.

2. Applicability

These terms apply whenever the Institution becomes engaged in U.S. federally-supported* (i.e., conducted or supported) human subject research, which is not otherwise exempt from the U.S. Federal Policy for the Protection of Human Subjects. The Institution becomes engaged whenever (a) the Institution's employees or agents intervene or interact with human subjects for purposes of U.S. federally-supported research; (b) the Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of U.S. federally-supported research; or (c) the Institution receives a direct award to conduct U.S. federally-supported human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
If a U.S. Department or Agency Head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided by the U.S. Federal Policy, the Department or Agency Head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided above consistent with the requirements of 101(h) of the U.S. Federal Policy.

[*Federally-supported is defined throughout the Assurance document and the Terms of Assurance as the U.S. Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves U.S. Government employees.]

3. Compliance with Regulations, Policies, or Guidelines

All U.S. federally-supported human subject research will comply with the requirements of any applicable U.S. Federal regulatory agency as well as one or more of the following:

a) The U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule (e.g., Subpart A)or the U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR 46 and its Subparts A, B, C, and D;

b) The May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4;

c) The 1993 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects;

d) The 1998 Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans;

e) The 2000 Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects; or

f) Other standard(s) for the protection of human subjects recognized by U.S. Federal Departments and Agencies which have adopted the U.S. Federal Policy for the Protection of Human Subjects.

4. IRB/IEC Written Procedures

a) The Institution should establish, and should provide a copy to OHRP upon request, written procedures for:

1) ensuring prompt reporting to the IRB/IEC, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any: (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance with the Federal Regulations or IRB requirements, and (iii) suspension or termination of IRB approval.

2) Verifying, by a qualified person or persons other than the investigator or research team, whether proposed human subject research activities qualify for exemption from the requirements of the U.S. Common Rule;

b) The designated IRB(s)/IEC(s) should establish, and should provide a copy to OHRP upon request, written procedures for:

1) Conducting IRB/IEC initial and continuing review (not less than once per year), approving research, and reporting IRB/IEC findings to the investigator and the Institution;

2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB/IEC review;

3) Ensuring that changes in approved research protocols are reported promptly and are not initiated without IRB/IEC review and approval, except when necessary to eliminate apparent immediate hazards to the subject.

5. Responsibilities and Scope of IRB(s)/IEC(s)

Except for research exempted or waived in accordance with sections 101(b) or 101(i) of the U.S. Common Rule, U.S. federally-supported research should be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the designated IRB(s)/IEC(s). The IRB (s)/IEC(s) should have authority to approve, require modifications in, or disapprove the covered human subject research.

6. Informed Consent Requirements

Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the U.S. Common Rule, informed consent should be:

a) sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section 116 of the U.S. Common Rule;

b) appropriately documented, in accordance with, and to the extent required by Section 117 of the U.S. Common Rule.

7. Considerations for Special Class of Subjects

For DHHS-supported human subject research, this Institution will comply with 45 CFR 46 Subparts B, C, and D prior to the involvement of pregnant women or fetuses, prisoners, or children, respectively. For non-DHHS U.S. federally-supported human subject research, the Institution will comply with any human subject regulations and/or policies of the supporting Department or Agency for these classes of subjects.

8. Requirement for Assurances for Collaborating Institutions/Investigators

The Institution is responsible for ensuring that all institutions and investigators engaged in its U.S. federally-supported human subject research operate under an appropriate OHRP or other federally-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of the supporting Department or Agency and the institution holding the Assurance.

9. Written Agreements with Non-Affiliated Investigators

The engagement in human research activities of each independent investigator who is not an employee or agent of the Institution may be covered under the FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the Institution may develop its own commitment agreement. Institutions must maintain commitment agreements on file and provide copies to OHRP upon request.

10. Institutional Support for the IRB(s)/IEC(s)

The Institution should provide the IRB(s)/IEC(s) that it operates with resources and professional and support staff sufficient to carry out their responsibilities under the Assurance effectively.

11. IRB(s)/IEC(s) Compliance with the Terms of Assurance

The Institution accepts and will follow items 1-10 above and is responsible for ensuring that (a) the IRB (s)/IEC(s) designated under the Assurance agree to comply with these terms, and (b) the IRB(s)/IEC(s) possesses appropriate knowledge of the local research context for all research covered under the Assurance (please refer to the OHRP posted guidance on IRB Knowledge of Local Research Context).

Any designation under this Assurance of another Institution's IRB or an independent IRB must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance. OHRP's sample IRB Authorization Agreement may be used for such purpose or the two organizations may develop their own agreement. This agreement should be kept on file at both organizations and made available to OHRP upon request.

12. Assurance Training

The OHRP Assurance Training Modules describe the major responsibilities of the Institutional Signatory Official, the Human Protection Administrator and the IRB Chair(s) that must be fulfilled under the Assurance. OHRP strongly recommends that the Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB/IEC Chair(s) personally complete the relevant OHRP Assurance Training Modules, or comparable training that includes the content of these Modules, prior to submitting the Assurance.

13. Educational Training

OHRP strongly recommends that the Institution and the designated IRB(s)/IEC(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB/IEC members and staff, and other appropriate personnel maintain continuing

knowledge of, and comply with, relevant ethical principles, relevant U.S. regulations; procedural standards under the Assurance; OHRP guidance; other applicable guidance; national, state and local laws; and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB/IEC members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.

14. Renewal of Assurance

All information provided under this Assurance should be updated every 36 months (3 years), even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's Federalwide Assurance for the protection of human subjects.

INTERNATIONAL INSTITUTIONS ACCEPTING THESE TERMS MAY PROCEED WITH THE ASSURANCE FILING PROCESS

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New Filing Ξ Update or Renewal for FWA Number: FWA00000327

U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions

1. Institution Filing Assurance

Legal Name: Washington State Department of Health

City: Olympia State: Washington

DHHS Institution Profile File (IPF) code, if known:

Federal Entity Identification Number (EIN), if known: 91-1444-603

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

G Please check here if there are no additional components or alternate names.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)
Environmental Health Programs Epidemiology, Health Statistics, and Public Health Laboratories Community and Family Health Health Systems Quality Assurance	**Olympia**	**Washington**

3. Statement of Principles

This Institution assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document(s). (*indicate below*)

Ξ ***The Belmont Report***

Other *(please submit copy to OHRP with this Assurance)*

4. Applicability

(a) This Institution assures that all of its activities related to federally-conducted or -supported human subject research will comply with the **Terms of Assurance for Protection of Human Subjects for Institutions Within the United States**. NOTE: The Terms of Assurance are contained in a separate document on the OHRP website.

(b) *Optional:* This Institution elects to apply the following to all of its human subject research regardless of source of support:

Ξ ***45 CFR 46 and all of its subparts (A,B,C,D)***

Common Rule (e.g., 45 CFR 46, subpart A)

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance *(if the IRB is not previously registered with DHHS or has not provided a membership roster to DHHS, please attach the appropriate IRB registration materials available on the OHRP website).*

NOTE: Reliance on another institution's IRB or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions involved may develop their own agreement. Future designation of other IRBs requires update of the FWA.

DHHS IRB Registration Number	Name of IRB As Registered with DHHS
IRB00000093	Washington State Institutional Review Board #1
IRB00000094	Washington State Institutional Review Board #2
	Fred Hutchinson Cancer Rsch Ctr -
IRB00000021	IRB1
IRB00000022	IRB2
IRB00000241	U Washington IRB #1 Committee A
IRB00000242	U Washington IRB #2 – B
IRB00000243	U Washington IRB #3 – C
IRB00000727	U Washington IRB #4 – D
IRB00002532	U Washington IRB #5 - G

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Michael Middle Initial: A. Last Name: Garrick

Degrees or Suffix (e.g., MD, PhD): Ph.D.

Institutional Title: Executive Secretary, Washington State Institutional Review Board

Institution: Department of Social and Health Services

Telephone: 360 902-8075 FAX: 360 902-0705 E-Mail: garrima@dshs.wa.gov

Address: DSHS Human Research Review Section, P.O. Box 45205

City: Olympia State: WA Zip Code: 98504-5205

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s) will comply with the **Terms of Assurance** and possess appropriate knowledge of the local context in which this Institution's research will be conducted. I understand that all collaborating institutions engaged in federally-conducted or -supported human subject research must submit their own Assurance.

All information provided with this Assurance is up to date and accurate. *I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature: Mary C Selecky Date: 4-13-04

First Name: Mary Middle Initial: C. Last Name: Selecky

Degrees or Suffix (e.g., MD, PhD): Institutional Title: Secretary

Telephone: 360 236-4030 FAX: 360 586-7424 E-Mail: mary.selecky@doh.wa.gov

Address: Department of Health, PO Box 47890

City: Olympia State: WA Zip Code: 98504-7890

NOTE: Facilities operated by the U.S. Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding this Assurance to OHRP.

8. DHHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to DHHS by the above Institution is hereby approved.

Assurance Number: FWA00000327 Expiration Date: 4/27/2007

Signature of DHHS Approving Official: Jean M. Makle Date: 4/27/2004

Jean M. Makle
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